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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,424	09/24/2003	Frank Berendes	CH-7929/LeA 36,206	5072
27384 7590 11/08/2007 NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			EXAMINER RAHMANI, NILOOFAR	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 11/08/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/669,424	Applicant(s) BERENDES ET AL.	
	Examiner Niloofer Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 10-16, and 19-20 are pending in the instant application.

Claims 1-9, 17-18, and 21-24 are cancelled.

2. ***Priority***

This application is RCE filed on 03/13/2007, which claims the priority of GERMANY 10244811.6, filed on 09/26/2002.

3. The rejection of claims 10-16, and 19-24 under 35 U.S.C. 112, first for the term “reducing” is withdrawn for reason of applicants argument in paper dated 05/10/2007.

4. The rejection of claims 10-16, and 19-24 under 35 U.S.C. 112, first for the term “cell preparations” is withdrawn for reason of applicants amendment and argument in paper dated 05/10/2007.

5. The rejection of claims 10-16, and 19-24 under 35 U.S.C. 112, first, as failing to comply with the written description requirement for the term “microorganism” is withdrawn for reason of applicants argument in paper dated 05/10/2007.

6. The rejection of claims 10-16, and 19-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for “microorganism” is maintained for reason of record. Applicants argue that the term “microorganism” has changed to “*Saccharomyces cerevisiae* NG 247, *Saccharomyces cerevisiae* Y278 and *Geotrichum candidum* ATCC 34614”, which are supported by instant Examples 1-5. Applicants also

argue that the strains recited in the claims are already accessible to the public and, therefore, a deposit is not necessary in this particular case. It is examiner's position that claims 10-16, and 19-24 are drawn to microorganism with no limitation to the species. There is no record for any deposit in the prosecution record. What species in the genus "microorganism" makes the compound or do the entire genus "microorganism" make the compound? Under what conditions is this compound made? If so, then enablement is needed for that. Any species embraced by the genus including future development must be deposited in compliance with MPEP§ 2404.

To satisfy the enablement requirement a deposit must be made "prior to issue" but need not be made prior to filing the application. *In re Lundak*, 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985).

MPEP

37 CFR 1.803(d) indicates that once a depository is recognized as suitable for the purposes of this rule, or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office. A current list (as of January, 1998) of IDAs recognized under the Budapest Treaty, with addresses, is included below. The mere fact that a deposit has been made in one of these depositories does not mean that the terms of the deposit meet either the requirements of the Budapest Treaty or the deposit regulations. Many of the depositories recognized under the Budapest Treaty have many different arrangements under which biological material may be stored.

37 CFR 1.808 requires that the deposit of biological material be made under two conditions:

(A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C.

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122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. The one exception that is permitted is specified in 37 CFR 1.808(b) which permits the depositor to contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent, meets any one or all of the three conditions specified in this paragraph. These conditions are: (A) the request is in writing or other tangible form and dated; and /or (B) the request contains the name and address of the requesting party and the accession number of the deposit; and /or (C) the request is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished. It should be noted that this exception to the general rule that all restrictions will be removed must be strictly followed and that no variations of this explicit exception will be accepted as meeting the conditions of this section. Although this exception is consistent with the provisions in the Budapest Treaty and its implementing regulations (Rule 11.4), other conditions on accessibility are permitted under the Budapest Treaty as prescribed by national law. Consequently, the mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these regulations except the requirement that all restrictions on access be removed on grant of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

The specification does not satisfy the Budapest Treaty and US required assertion of removal of all restrictions. As such, the deposit in the specification is insufficient for US Practice. MPEP 2402 specifically identifies the criteria necessary if the deposit was not made according to the Budapest Treaty.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

11/02 /2007

NR



MARGARET D. SEAMAN

PRIMARY EXAMINER

GROUP 1625